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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,315	04/08/2008	Lawrence Solomon	1322-035	2612

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EXAMINER	
SASAN, ARADHANA	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
05/24/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOmail@hgcpatent.com
ipdocket@hgcpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,315	SOLOMON ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,7-12 and 15-33* is/are pending in the application.

4a) Of the above claim(s) *27-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,7-12,15-26 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/20/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks, amendments, and Request for Continued Examination filed on 04/20/11 are acknowledged.

2. Claims 2, 4-6, and 13-14 were previously cancelled. Claims 27-32 were previously withdrawn.

3. Claim 1 was amended.

4. Claims 1, 3, 7-12, 15-26 and 33 are included in the prosecution.

Continued Examination under 37 CFR 1.114

5. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/20/11 has been entered.

Information Disclosure Statement

6. The information disclosure statement (IDS) filed on 04/20/11 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

Response to Arguments

Rejection of claims under 35 USC § 103(a)

7. Applicant's arguments, see Page 6, filed 04/20/11, with respect to the following rejections under 35 USC § 103(a) have been fully considered and are persuasive.

- Rejection of claims 1, 3, 7-12, 15-17, 21-26 and 33 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447)
- Rejection of claims 17-18 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Addicks et al. (US 5,041,430)
- Rejection of claims 17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Eberlin et al. (US 3,696,091)
- Rejection of claims 17 and 20 under 35 U.S.C. 103(a) as being unpatentable over Langauer (US 3,723,614) in view of Ting et al. (WO 00/18447) and further in view of Franz et al. (US 6,555,581 B1)

Therefore the rejections of 01/20/11 are withdrawn.

However, upon further consideration, a new ground(s) of rejection is made over Hess et al. (CH648754 – English Translation provided by Applicant).

New Objections/Rejections

Claim Objections

8. Applicant is advised that should claim 17 be found allowable, claim 33 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

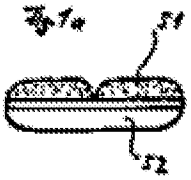
> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3, 7-9, 11-12, 15, 17 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Hess et al. (CH648754 – English Translation provided by Applicant).

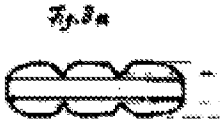
The claimed invention is a compressed, layered pharmaceutical tablet comprising one or more layers forming a first inactive segment containing either an undetectable amount of drug or a pharmaceutically ineffective amount of drug, the inactive segment having a top and bottom face wherein only one of the faces contacts an active layer containing a drug or drugs, and the active layer being scored to form substantially identical first and second unitary segments each having a top and bottom

face wherein only one of the faces of each unitary active segment contacts the first inactive segment.

Hess teaches a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided (Abstract, Fig. 1, and Example 1 - Page 4).



Regarding instant claims 1 and 15, the limitations of the tablet are anticipated by Figure 1 which shows a multi-layer (layer S1 and layer S2) tablet with a single break groove; wherein the active is present in one layer (S1) and there is a placebo (i.e., inactive) layer that does not contain a drug, as taught by Hess (Page 4).



Regarding instant claim 3, the limitation of additional unitary segments in addition to the first and second unitary segments that are derived from the same layer or layers as the first unitary segment is anticipated by Figure 3a which shows a tablet that may be divided into three parts, as taught by Hess.

Regarding instant claims 7-9, the limitations of the inactive layer are anticipated by the layer (S2) which does not contain a drug, as disclosed by Hess (Fig. 1 and Page 4).

Regarding instant claim 11, the limitation of the granulation containing a drug is anticipated by the active ingredient granulation taught by Hess (Page 4, Example 1).

Regarding instant claim 12, the limitation of the first and second unitary segments that are outer segments is anticipated by the outer segments taught by Hess (Figure 3a).

Regarding instant claims 17 and 33, the limitation of the drug that is effective in the treatment of cardiovascular conditions is anticipated by the metoprolol tartrate taught by Hess (Page 4, Example 1).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 10, 16 and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507).

Hess is discussed above.

Hess does not expressly teach a granulation that does not contain a drug.

Schmidt teaches a multi-layered tablet comprising one or more layers free from active substance and a layer containing an active substance (Abstract). Schmidt discloses advantages of the normal sized tablets that provide ease of handling and division (Col. 3, lines 11-24). Preparation of a multi-layer tablet is disclosed (Col. 3, lines 49-64 and Col. 4, lines 1-7). The example discloses that the placebo composition is prepared in the same way as the active granulation (Col. 4, lines 21-54).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which

contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to use a known technique (preparing a placebo or inactive layer composition in a multi-layer tablet by granulating the placebo composition – as taught by Schmidt) to improve similar products (multi-layered tablet containing an active layer and a placebo or inactive layer – as taught by Hess). Please see MPEP 2141.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 10, the limitation of a granulation that does not contain a drug would have been obvious over the granulation of the placebo composition as taught by Schmidt (Col. 4, lines 21-54).

Regarding instant claim 16, the limitation of two additional unitary segments which are compositionally identical would have been obvious over the multilayered tablets, as taught by Hess (Abstract, Figures 1 and 3, and Page 4) in view of the multilayered tablets which may have one or more layers free from active substance, as taught by Schmidt (Abstract, Col. 3, lines 19-21 and Col. 4, lines 21-54). One of ordinary

skill in the art would find it obvious to provide a plurality of layers or segments and manipulate these layers or segments based on the desired dosage form.

Regarding instant claims 21-22, the limitations of the first and second segments would have been obvious over the divisible tablet taught by Hess (Abstract, Fig. 1, Page 4) and by the multi-layered tablet taught by Schmidt (Abstract, Col. 3, lines 49-64 and Col. 4, lines 1-7 and lines 21-54). One of ordinary skill in the art would find it obvious to arrange and manipulate the plurality of layers or segments during the process of routine experimentation based on the desired dosage form.

Regarding instant claims 23-26, the limitations of a method of breaking the pharmaceutical tablet and the method of administering a partial dose of a drug from the tablet would have been obvious over the divisible tablet taught by Hess (Abstract, Fig. 1, Page 4) and by the multi-layered tablet taught by Schmidt (Abstract, Col. 3, lines 49-64 and Col. 4, lines 1-7 and lines 21-54). One of ordinary skill in the art would find it obvious to break and divide the breakable tablets taught by Hess and Schmidt based on the desired dosage of drug to be administered since these are the advantages associated with divisible tablets (Hess – Abstract and Schmidt – Col. 3, lines 16-18).

13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507), and further in view of Nesselroad, III (US 2004/0167207 A1).

Hess and Schmidt are discussed above.

Hess and Schmidt do not expressly teach the drug warfarin.

Nesselroad teaches that tablets of warfarin were halved along their scoring lines in order to create smaller dosage steps between doses of warfarin and for easy daily dosing (Page 5, [0043]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, in view of the use of warfarin as an active drug in a multi-scored pharmaceutical tablet, as taught by Nesselroad, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because divisible tablets with warfarin (tablets with scoring lines) were known in the art, as evidenced by the teaching of Nesselroad. Moreover, Nesselroad teaches the desirability of creating smaller dosage steps between doses of warfarin since “at the lower warfarin

doses, the interval between easily taken amounts is a significant dose change" (Page 5, [0043]).

Regarding instant claim 18, the limitation of warfarin would have been obvious over the tablets of warfarin that were halved along their scoring lines as taught by Nesselroad (Page 5, [0043]).

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507), and further in view of Eberlin et al. (US 3,696,091).

Hess and Schmidt are discussed above.

Hess and Schmidt do not expressly teach the drug digoxin.

Eberlin teaches a tablet that comprises digoxin (Col. 12, lines 20-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, in view of the tablet that comprises digoxin, as taught by Eberlin, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to combine prior art elements according to known methods (incorporating

digoxin in a tablet and preparing a multilayered, divisible tablet) to yield predictable results. Please see MPEP 2141.

Regarding instant claim 19, the limitation of digoxin would have been obvious over the tablet of digoxin as taught by Eberlin (Col. 12, lines 20-45).

15. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. (CH648754 – English Translation provided by Applicant) as applied to claims 1, 3, 7-9, 11-12, 15, 17 and 33, in view of Schmidt (US 4,786,507), and further in view of Franz et al. (US 6,555,581 B1).

Hess and Schmidt are discussed above.

Hess and Schmidt do not expressly teach the drug levothroxine.

Franz teaches a tablet that comprises levothyroxine sodium (Col. 17, Table 1, lines 10-22).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a compressed, layered pharmaceutical tablet that has a dividing groove located on one side so that the tablet can be easily divided and which contains an active layer and a placebo layer, as taught by Hess, prepare the placebo composition in the form of a granulation, as taught by Schmidt, further combine it with the tablet that comprises levothyroxine, as taught by Franz, and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because it is obvious to combine prior art elements according to known methods (incorporating levothyroxine in a tablet and preparing a multilayered, divisible tablet) to yield predictable results. Please see MPEP 2141.

Regarding instant claim 20, the limitation of levothroxine would have been obvious over the levothyroxine in the tablet taught by Franz (Col. 17, Table 1, lines 10-22).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615